

Applicants: Florack et al.
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REMARKS

In the Restriction Requirement, the Examiner alleges that the application contains the following groups of inventions which allegedly are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Group I: claims 1-11, and 18-20 – drawn to a protein complex comprising at least two, preferably identical subunits wherein at least one subunit is unaltered and at least one subunit is fused to a first molecule of interest and wherein the protein complex is able to interact with a cell surface receptor via said subunits.

Group II: claims 12-14 – drawn to a method for producing a protein complex according to claim 1.

Group III: claims 15-18 and 24-25 – drawn to a cell comprising the protein complex according to claim 1.

Group IV: claims 21-23 – drawn to use of a protein complex according to claim 1 as a mucosal carrier molecule and a method for modulating an immune response comprising administering at least one dose of an effective amount of a protein complex according to claim 1 wherein the molecule of interest is an antigen and a method for mucosal immunization comprising the vaccine of claim 19.

In response, Applicants elect Group I, claims 1-11 and 18-20, with traverse. Upon electing Group I, Applicants have been further required to elect a single species from (1) enterotoxin of *E. coli* or (2) cholera toxin, and a single species from (1) bacterial antigen, (2) viral antigen, (3) protozoal antigen, (4) fungal antigen, (5) cytokine, or (6) heat shock protein.

In response, Applicants elect enterotoxin of *E. coli* and bacterial antigen as the species of toxin and antigen, respectively. The claims have been amended accordingly.

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The claims have been amended in accordance with Applicant's response to Restriction Requirement. Claim 8 has been cancelled, claims 3 and 7 have been amended, and claims 12-17 and 21-25 have been withdrawn. Presently, claims 1-11 and 18-20 are pending consideration.

Applicant's traverse the Restriction Requirement for the following reasons. According to the Examiner, the linking concept of the invention (a protein complex having at least two, preferably identical subunits wherein at least one subunit is unaltered and at least one subunit is fused to a first molecule of interest) is anticipated by Arntzen, et al. (WO 96/12801).

Applicants respectfully disagree. Arntzen et al. do not teach a complex of the invention. Specifically, Arntzen et al. do not teach a complex wherein at least one subunit is unaltered and one or more of the others is fused to a protein of interest. Applicants respectfully point the Examiner to page 5, lines 1-7 of the application where it is clear that the invention is specifically directed to complexes wherein not all subunits are fused to a protein of interest, such as an antigen. Furthermore, the application specifically states that the SEKDEL hexapeptide is not comprised in the definition of a protein of interest according to the invention. In fact, subunits fused to a SEKDEL sequence are regarded as unaltered subunits. See page 6, lines 1-6 of the application.

According to the terms of the present application, the complex of Arntzen et al. is a complex with six unaltered subunits. Arntzen et al. lack the required at least one subunit fused to a first molecule of interest. Thus, Arntzen et al. do not anticipate the linking concept of the present invention. Reconsideration and withdrawal of the Restriction Requirement is respectfully requested.

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If the Examiner believes that a telephone discussion with Applicant's representative would be helpful to clarify any remaining issues, he/she is invited to contact the undersigned.

Respectfully submitted,



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